This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 33-R-0008
CUSTOMER NUMBER: 694

FORM APPROVED
OMB NO. 0579-0036

I I T Research Institute
10 West 35th Street
Chicago, IL 60616

Telephone: (312) -567-4000

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	127	78	14	0	92
5. Cats					
6. Guinea Pigs	253	290	0	520	810
7. Hamsters					
8. Rabbits	9	51	1	0	52
9. Non-human Primates	42	41	0	1	42
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATU (b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

DATE SIGNED 11/15/07

APHIS FC (AU ch is obsolete.)

Column E Explanation

1. **Registration Number:** 33-R-0008

2. **Number of animals used in this study:** 160 X 4 studies

3. **Species (common name) used:** Hartley guinea pigs

4. **Number of animals placed in Column E:** 520 (130/study)

5. **Explain the procedure producing pain and/or distress:**

   These four studies were conducted to verify the potency of vaccines for the following diseases: Venezuelan Equine Encephalitis, Trinidad strain (2 studies); Western Equine Encephalitis, b-11/65 strain; and Eastern Equine Encephalitis, PE-6 strain. Animals receiving vaccines at lower vaccine dilutions or receiving no vaccines at all, in all likelihood experienced distress due to the pathogenesis of the viruses.

6. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results:**

   Use of narcotic analgesic agents can cause histamine release (Soma, 1983) and respiratory depression, which could alter the pathogenic and clinical response to infection. Also, NSAIDs (non-steroidal anti-inflammatory drugs) block the anti-inflammatory response which could alter the pathogenic and clinical response to infection.

7. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations title number and the specific section number:**

   Agency: FDA – Bulletin #99 – "Guidance for Industry. Stability Testing of New Biotechnological/Biological Veterinary Medical Products VICH GL17 Final Guidance, March 26, 2001"

   CFR:

Column E Explanation

1. **Registration Number:** 33-R-0008

2. **Number of animals used in this study:** 32

3. **Species (common name) used:** Cynomolgus monkeys

4. **Number of animals placed in Column E:** 1

5. **Explain the procedure producing pain and/or distress:**

   This was an oral gavage safety assessment (toxicity) study of a pharmaceutical product for submission to the FDA. One animal developed mild to moderate dyspnea (labored breathing) and stopped eating. The test material was a liquid that was administered via stomach tube. The animals were not sedated for dosing. This animal died unexpectedly. Gross necropsy findings and histopathological assessments were consistent with aspiration pneumonia. This condition was caused either by aspiration of vomitus or as a result of a dosing error.

6. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results:**

   Supportive treatment was administered to this animal with initial positive results. Tranquillization for relief of apprehension and/or distress was considered by the veterinary staff but was dismissed due to the likelihood of causing additional respiratory depression and distress.

7. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations title number and the specific section number:**

   Agency: FDA – "Guidance for Industry and Other Stakeholders - Toxicological Principals for the Safety Assessment of Food Ingredients – Redbook 2000"

   CFR: